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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,663	11/29/2001	Lorraine Faxon Meisner	121753-1004	5796

7590 02/26/2002

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,663

Applicant(s)

MEISNER, LORRAINE FAXON

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Priority

Please update status of Application Serial No. 09/356,142 by inserting "now Patent No. 6,217,914," after "July 19,1999".

Specification

The disclosure is objected to because of the following informalities: Pg. 9, line 24, "FIGURES" should be "DRAWINGS".

Appropriate correction is required.

Claim 19 is objected to because of the following informalities: Claim 19, line 3, the "a" before "(a)" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed process of pretreating the ascorbic acid and ascorbic acid which has been pretreated according to said process in the disclosed amounts and temperatures, does not reasonably provide enablement for other processes of pretreating the ascorbic acid or ascorbic acid pretreated by other processes. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The Specification does not appear to disclose any other method of pretreating ascorbic acid. As such, one of ordinary skill in the art would be required to due undue experimentation in order to determine what other methods would be suitable for pretreating the ascorbic acid which results in the same or similar characteristics of the disclosed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the process steps by which the ascorbic acid is pretreated. The Specification explicitly discloses that between 10% and 50% of the ascorbic acid is pretreated and/or stabilized by heating a specified concentration of ascorbic acid at a specified temperature range and pH of at least 3.5 (Pg. 8, lines 3-10, Pg. 9, lines 7-15). The Specification does not appear to disclose or suggest alternative methods of pretreating the ascorbic acid, as such, the process appears to be critical to the invention and should be included in the claims.

Claims 1-17, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 17 recite "10%" which renders the claim indefinite as it is uncertain what the basis for the percent is, i.e. weight, volume, weight/volume, weight/weight, etc. Because claims 2-26 are dependent on claim 1 and do not cure the rejection said claims are also rejected.

Claim 9, 20 recites “microspheres and other encapsulants” which renders the claim indefinite as it is uncertain what is and what is not included in the scope of “other encapsulants” as opposed to “microspheres”. Examiner suggest that Applicant simply list “encapsulants” separately in the list.

Claims 9, 20 recite the transitional phrase “comprises” which renders the claim indefinite as using the transitional phrase without repeating the limitations of claims 1,13, respectively, implies their absence such that the composition need only be limited by the limitations specifically set forth in claims 9, 20. Examiner suggests “wherein the composition is in the form of” or “wherein the composition is formulated as”.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claims 9, 20 recite the broad recitation “microspheres and other encapsulants”, and the claim also recites “time-release encapsulants” which is the narrower statement of the range/limitation. Claim 11 recites “(j) one or more tissue compatible vehicles” and the claim also recites “one or more humectants or moisturizers”. Claim 16 recites “teflon” and “polytetrafluoroethylene”.

Claim 11 recites “(o) any combination of (a)-(o)” which renders the claim indefinite as it appears to be redundant to list “o” as part of the combination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (U.S. Pat. 4,938,969) in view of Murad (U.S. Pat. 5,902,591) and Herstein (U.S. Pat. 5,902,591).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucosamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers

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and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule and that the ascorbic acid is kept separate until point of use (Column 10, lines 6-17).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of pretreated ascorbic acid. However, the prior art amply suggests the same the term "pretreatment" is not defined in the claim, as such, keeping the ascorbic acid separate until point of use appears to fall within the scope of said term. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of said components would effectively treat and reduce wrinkles and increase the stability of the ascorbic acid present within the composition.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,217,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the Application and Patent claims compositions and methods for treatment of skin containing pretreated ascorbic acid and tyrosine, zinc, and/or glucosamine or other anti-inflammatory compounds.

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-51 of U.S. Patent Application No. 09/732,385 in view of the claims 1-35 of U.S. Pat. No. 6,217,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Applications and Patent claim methods for treatment of skin containing pretreated ascorbic acid and tyrosine, zinc, and/or glucosamine or other anti-inflammatory compounds. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the method claims into compositions with the expectation that the compositions would be effective in treating various skin conditions.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of U.S. Pat. Application No. 09/732,385 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

February 22, 2002


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

